



March 14, 2005

United States
Department of
Agriculture

Animal and Plant
Health Inspection
Service

Veterinary Services

Center for Veterinary
Biologics

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The Honorable Jon Dudas
Under Secretary for Commerce for Intellectual Property and
Director of the United States Patent and Trademark Office
Mail Stop Patent Extension
PO Box 1450
Alexandria, VA 22313-1450

Dear Director Dudas:

This is in regard to the application for patent term extension for U.S. Patent No. 5,275,813, filed by the Regents of the University of California, under 35 U.S.C. § 156. The veterinary biologic product claimed by the patent is Fel-O-Vax® FIV vaccine (Feline Immunodeficiency Virus Vaccine, Killed Virus), which was assigned VS Code No. 15A5.21 by the Center for Veterinary Biologics (CVB).

In the May 8, 2003, issue of the Federal Register (68 Fed. Reg. 24705-24706, Docket No. 03-045-1), the CVB published its determination of this product's regulatory review period, as required under 35 U.S.C. § 156(d)(2)(A). The notice provided that on or before November 4, 2003, 180 days after the publication of the determination, any interested person could file a petition with the CVB under 35 U.S.C. § 156(d)(2)(B)(i) for a determination of whether the patent term extension applicant acted with due diligence during the regulatory review period.

The 180-day period for filing a due diligence petition pursuant to this notice has expired and the CVB has received no such petition. Therefore, the CVB considers the regulatory review period determination to be final.

Please let me know if we can provide further assistance.

Sincerely,

Richard E. Hill, Jr.
Director
Center for Veterinary Biologics

cc:

Kevin L. Bastian, Townsend & Townsend & Crew, San Francisco, CA



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